

REMARKS

Applicant's undersigned attorney thanks the Examiner for his comments. Applicant respectfully requests reconsideration of this patent application, particularly in view of the above Amendment and the following remarks.

Applicant's invention is a composition including a microbiological culture media for producing a stabilized dihydrolipoic acid (DHLA) compound derived from a once-living source, i.e., at least one probiotic organism. Such stabilized DHLA is suitable for use in a medicament and/or nutritional supplement. The microbiological culture media includes at least one live probiotic organism capable of producing a stabilized DHLA compound, R-lipoic acid and at least one nutritive agent.

Amendment to the Claims

Claims 4-22 are pending with Claim 13-19 withdrawn. Claims 4-12 and 20-22 have been examined with no claims allowed.

Claims 4 and 21 have been amended to recite a composition comprising a microbiological culture media for producing a stabilized dihydrolipoic acid compound. The preamble of Claims 5-12 and 22 has been amended accordingly.

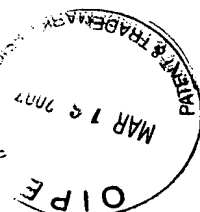
Claims 12 and 22 have been further amended to recite that the microbiological culture media comprises select components.

Claim 12 has been additionally amended to recite that that microbiological culture media comprises about 40 composition weight percent of a paste and that the paste includes at least one live probiotic organism.

Claim 20 has been amended to recite a microbiological culture media, thus correcting a typographical error. Claim 20 has been further amended to clarify that the at least one probiotic organism is capable of producing the stabilized dihydrolipoic acid compound.

New Claim 23 is an independent claim and is directed to a microbiological culture media for producing a stabilized DHLA compound consisting of at least one live probiotic organism, R-lipoic acid and tumeric rhizome.

No new matter has been added by this Amendment. Applicant believes that no fees are owed because the number of claims currently pending does not exceed the number originally paid for.



Claim Rejections – 35 USC §112

The rejection of Claim 12 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention, is respectfully traversed.

Claim 12 has been amended to recite that the microbiological culture media includes about 40 composition weight percent of a paste, about 20 composition weight of R-lipoic acid and 40 composition weight percent tumeric rhizome powder. Applicant submits that one skilled in the art would understand that such composition weight percentages are based upon total weight of the microbiological culture media, particularly given that recited composition weight percentages total 100%.

Applicant has further amended Claim 12 to clarify that the paste, which constitutes 40% of the total weight of the microbiological culture media, includes at least one live probiotic organism. Applicant respectfully submits that one skilled in the art and guided by the teachings provided would understand and be enabled to prepare a suitable paste containing at least one live probiotic organism to produce a stabilized DHLA compound.

For at least the reasons above, amended Claim 12 is not indefinite. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

The rejection of Claim 20 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention, is respectfully traversed.

Claim 20 has been amended to clarify that the at least one live probiotic organism is capable of producing a stabilized DHLA compound. Thus, contrary to the Examiner's interpretation, Claim 20 should be read as further limiting the class(es) of live probiotic organisms which can be included in the microbiological media. Thus, the at least one probiotic organism is not used in a medicament or a nutritional supplement but, instead, is capable of producing a stabilized DHLA compound for use in a medicament or a nutritional supplement.

For at least the reasons above, amended Claim 20 is not indefinite. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claim Rejections – 35 USC §103

The rejection of Claims 4-10 and 20-22 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,368,617 to Hastings et al. in view of Hermann et al (European Journal of Pharmaceutical Sciences, 1996) is respectfully traversed.

The core of Applicant's invention is a composition in the form of a microbiological culture media for producing a stabilized DHLA compound that has been derived from a once-living source. Such stabilized DHLA, when consumed as part of a medicament and/or a nutritional supplement, is believed to be capable of sustaining cellular DNA within the body. The stabilized DHLA is produced by feeding a live probiotic organism R-lipoic acid and at least one nutritive agent such as, for example, tumeric rhizome. The live probiotic organisms in the microbiological culture media produce a stabilized DHLA compound via a metabolic conversion process.

In contrast, Hastings discloses a dietary supplement for promoting health hormone balance in adult human subjects that comprises a secretagogue known as Symbiotropin in combination with 7-ketodehydroepiandrosterone (7-keto DHEA). The dietary supplement may further include one or more of alpha-lipoic acid, a probiotic blend of *Bifidobacterium bifidum* and *Lactobacillus acidophilus*, fructo-oligosaccharides and various other components. Hermann discloses that R(+)-enantiomer of alpha-lipoic acid has a greater absolute bioavailability than the S(-)-enantiomer of alpha-lipoic acid.

To establish prima facie obviousness of a claimed invention, all of the claim limitations must be taught or suggested by the prior art. Claims 4 and 21 recite a composition comprising a microbiological culture media for producing a stabilized DHLA compound. However, Hastings in view of Hermann does not disclose or suggest that a composition, which is not intended to be consumed, comprising a secretagogue known as Symbiotropin in combination with 7-keto DHEA can be used to produce a stabilized DHLA compound.

In the present instance, Applicant is not combining two composition each taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose but has developed a composition

useful for an entirely different purpose; that of producing a stabilized DHLA compound.

For at least the reasons above, Hastings in view of Hermann does not disclose or suggest a composition comprising a microbiological culture media for producing a stabilized DHLA compound as recited in amended Claims 4 and 21. Because Claims 5-10 and 20 depend from Claim 4 and Claim 22 depends from Claim 21, these claims are also patentable over Hastings in view of Hermann. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

The rejection of Claims 11 and 12 under 35 U.S.C. § 103(a) as unpatentable over Hastings in view of Hermann and further in view of U.S. Patent 6,080,401 to Reddy et al. is respectfully traversed.

As discussed above, Hastings in view of Hermann does not disclose or suggest a composition comprising a microbiological culture media for producing a stabilized DHLA compound.

Reddy discloses drugs containing a combination of beneficial micro-organisms, such as probiotic organisms, with drugs of herbal origin, such as *curcuma longa*, for the treatment of a disease or disorder in humans or animals. Reddy, similar to Hastings in view of Hermann, does not disclose or suggest that such combinations can be used as a microbiological culture media for producing a stabilized DHLA compound.

Further, the concentrations provided for the constituents of the microbiological culture media necessarily have criticality. Applicant has determined that such disclosed concentrations are necessary to support the production of a stabilized DHLA compound. Additionally, Hastings in view of Hermann and further in view Reddy does not disclose or suggest a microbiological culture media including 40% of a probiotic organism-containing paste, about 20% R-lipoic acid and about 40% tumeric rhizome powder as recited in amended Claim 12.

For at least the reasons above, Claim 4 is patentable over Hastings in view of Hermann and further in view of Reddy. Because Claims 11 and 12 depend from Claim 4 these claims are also patentable over Hastings in view of Hermann and further in view of Reddy. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

If the Examiner feels that any issues remain regarding this application, then Applicant's undersigned attorney would like to discuss the case with the Examiner. The undersigned can be reached at (312) 327-3327.

Respectfully submitted,



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